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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,472	03/09/2001	Paz Einat	EINAT=4.1C	7736

1444 7590 10/14/2005

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WASHINGTON, DC 20001-5303

EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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10062005

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 09/802,472	Applicant(s) EINAT ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 19 September 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 16 and 17.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 9, 13 and 15.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

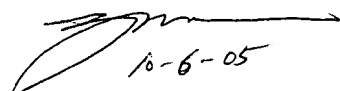
#### AFFIDAVIT OR OTHER EVIDENCE

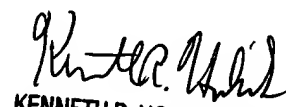
8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants amendment has been entered for the purpose of appeal. Applicants' arguments are addressed with respect to the claims that are pending as a result of the amendment. It should be noted that the rejection of claims 16 and 17 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the entered amendment. With regard to claims 9, 13, and 15, Applicants arguments have been fully considered but they are not found persuasive. Claim 13 is drawn to an isolated polypeptide encoded by: a) a polynucleotide comprising SEQ ID NO: 3; or b) a naturally occurring polynucleotide having at least 95% identity with a naturally occurring polynucleotide comprising SEQ ID NO: 3 and, in naturally occurring neural cells, has its expression modulated when the cells are subjected to neurotoxic stress, wherein the protein encoded by the polynucleotide of b) induces cell apoptosis when overexpressed in human epithelial breast carcinoma MCF-7 cells; or c) a naturally occurring polynucleotide capable of hybridizing under highly stringent conditions to polynucleotide comprising SEQ ID NO: 3, in a naturally-occurring neural cells, has its expression modulated when the cells are subjected to neurotoxic stress, wherein the protein encoded by the full-length cDNA having the sequence of c) induces cell apoptosis when overexpressed in human epithelial breast carcinoma MCF-7 cells. While embodiment a) of claim 1 meets the written description, embodiments b) and c) lack written description for the following reasons. The instant specification contains a single disclosure - a polynucleotide consisting of SEQ ID NO: 3. The specification, however, does not have any description for the polynucleotide species b) and c) which are drawn to that which has 95% homology or hybridizes to (under stringent condition) to SEQ ID NO: 3, and that these polynucleotides are also overexpressed in human epithelial breast carcinoma MCF-7 cells and induces apoptosis. One of skill in the art would not readily recognize that Applicants were in possession of the sub-genus claimed by embodiments b) and c) therefore. It should also be noted that embodiment c) embraces a "full-length" cDNA which hybridizes to SEQ ID NO: 3. The specification does not evidence that Applicants were in possession of at least one species that hybridizes to SEQ ID NO: 3, wherein said species is a full-length cDNA which also induces apoptosis when overexpressed. With regard to claim 9, the claim is drawn to a molecule which comprises the antigen-binding portion of an antibody specific for the protein or "variant" of claim 13. Additionally, Applicants own publication states that Hi95 gene, "seems to be involved in complex regulation of cell viability in response to different stress conditions," indicating that the cellular mechanism is one of complex one and that no direct evidence is present in whether its overexpression actually "induces" apoptosis. Finally, it goes without question that applicants were not in possession of any variant of a protein encoded by SEQ ID NO: 3. The term variant is interpreted in the art as that which is the same protein but existing in an alternative form (i.e., mutant). In other words, if a protein was a kinase, then one skilled in the art would know that variant protein would be a variant form of a kinase, but kinase nevertheless. However, the instant specification does not disclose what the function of the claimed protein is. Hence, one of skill in the art would not know that Applicants were in possession of any variant form thereof, would also not able to recognize that applicants were in possession of a composition that comprises the antigen-binding portion of an antibody specific for this variant. The rejection is maintained therefore.

  
10-6-05  
**YOUNG J. KIM**  
**PATENT EXAMINER**

  
**KENNETH R. HORLICK, PH.D**  
**PRIMARY EXAMINER**  
10/12/05